REMARKS

Claims 1-15, 17-20, 22, 23, 25, 27-30 are pending. Claims 16 and 26 have been cancelled without prejudice or disclaimer. Applicants thank the Examiner for indicating the allowance of claims 1-6, 8-10 and 12-15. However, in light of the above amendments and remarks which follow, Applicants respectfully present that each of the present claims are allowable.

I. Cited Documents

The Office Action indicates the references identified by the Information Disclosure Statements of March 16, 2006 and August 7, 2006 have been considered. However, the initialed forms provided with the Office Action contain lines through the identification of various documents, apparently indicating that such documents were not considered. Thus, Applicants respectfully request the Patent Office provide an unambiguous indication that all documents have been considered.

Applicants additionally take this opportunity to object to the citation and/or reliance upon particular documents identified in the Form PTO-892 mailed with the Office Action. Specifically, Non-Patent Document X is a Wikipedia article (an inherently unreliable source), showing a date of September 1, 2006, i.e., almost 1 year after the U.S. filing date of the present application. While Applicants do not necessarily disagree with the information/data discussed by this document, Applicants object to the citation and/or reliance upon this reference as "prior art," as it does not satisfy any of the requirements of 35 USC § 102. The Office Action additionally cites Non-Patent Document U, claiming a publication date of May 5, 2005. The present application is a § 371 national stage of PCT/GB2003/004981 (incorporated by reference in its entirety), having a filing date of November 18, 2003. Because the present claims are supported by at least the PCT application, Document U cannot qualify as "prior art" under 35 USC § 102.

II. Objections

Claims 7 and 11 and the abstract stand objected to for informal matters. In response, claims 7 and 11 and the abstract have been amended.

III. 35 USC § 112

Claims 23, 25 and 26 stand rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office Action asserts the specification does not describe the invention recited by these claims to permit one of ordinary skill in the art to make and use the invention. In light of the amendments, reconsideration is respectfully requested.

The Office Action states that these claims are directed to inhibiting ACE to any patient in need thereof, without giving any further instructions, e.g., dosages. As the Office Action believes the pharmaceutical art is "highly unpredictable," one of ordinary skill in the art would not know, based on the present specification, how to make and use the full scope of the claimed invention. Applicants respectfully disagree.

Claim 23 no longer recites the amount of the pharmaceutically acceptable salt of perindopril present in the composition and, thus, is not longer subject to the rejection.

The rejected claims 25 and 26 recite particular levels of perindopril sufficient to inhibit ACE. Determining what levels satisfy this requirement are rather simply determined by routine experimentation. The following everyday procedure is only one commonly understood method of determining the levels recited by the claims:

1. Measure ACE levels.
2. Administer perindopril.
3. Measure ACE levels again.

If the second measurement is less than the first measurement, it would be understood by even those of any basic skill in any scientific art that the selected level is a "an effective ACE inhibitory amount" of perindopril. The claims do not recite treating and/or curing any particular disease or bodily condition, only inhibiting ACE levels.

However, in the interests of advancing prosecution of this application, claims 23 and 25 have been amended, and claim 26 cancelled. Applicants expressly reserve the right to file one or more continuing application containing claims reciting the subject matter of these now-cancelled claims.

Claim 25 has been amended to recite a method of treating "at least one disease state selected from the group consisting of hypertension and congestive heart failure," as supported throughout the specification and claims.

Claim 23 has also been amended to recite that the composition comprises "a pharmaceutically acceptable salt of perindopril," and no longer recites "an effective ACE inhibitory amount."

Reconsideration is respectfully requested.

IV. 35 USC § 102

Claims 16 and 23 stand rejected under 35 USC § 102(b) as allegedly being anticipated by Vincent et al. (U.S. Patent No. 4,508,729). Claims 25 and 26 stand rejected under 35 USC § 102(b) as allegedly being anticipated by Straub et al. (U.S. Patent No. 6,932,983). In light of the amendments, reconsideration is respectfully requested.

Specifically, as claims 16 and 26 have been cancelled and claims 23 and 25 have been amended to depend from claim 17 (a claim not rejected as being anticipated by either Vincent et al. or Straub et al.), Applicants respectfully submit that this rejection is moot.

V. 35 USC § 103

Claims 17-20 and 22 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over Vincent et al. The Office Action asserts the hydrated salt of perindopril, as recited by these claims, is anticipated by Vincent et al. Vincent et al. is the basic patent for perindopril, however, this reference neither teaches nor suggests the hydrated salt of perindopril.

There is no explicit disclosure in Vincent et al. of a salt of perindopril; compound 17 in the table is perindopril, and it is not in the form of a salt. There is no explicit mention of any of the iminodiacids (of which perindopril is one) or salts thereof being in the form of a hydrate. There is no example relating to the preparation of perindopril.

The products produced by the method of Vincent et al. are not hydrated salts of perindopril as presently claimed in claims 17-20, 22 (and new claims 27, 28 and 29). The processes exemplified

by Vincent et al. (and which are said to have been used to produce the compounds in the Table, for example perindopril) do not result in the hydrate of the product. This is clear from the elemental analyses at the end of each example.

Examples 4 and 6 of the reference relate to processes for preparing compounds identical to perindopril apart from the propyl substituent. In these examples, following the formation of the crude product (in anhydrous ethanol and sodium borohydride), the crude product in solution is extracted with distilled water. The extraction refers to washing of the diethyl ether solution with water to remove inorganics. The subsequent step "then dried over calcium sulphate" refers to drying of the organic extract and not the water extract. The drying with calcium sulphate is essentially to remove traces of water present in the organic layer. Thus, there is no part of the process which would result in the hydrate.

In Examples 2, 3, 4 and 6 of the present application, perindopril erbumine monohydrate is generated because water is added to perindopril erbumine in an appropriate solvent. With regard to Example 5, the product isolated after filtration is exposed to a humidified atmosphere (of at least 75% humidity), which leads to the formation of the monohydrate. Thus, there are distinct process steps which have to be undertaken in order to produce the hydrate; the hydration state is not an inherent property of the perindopril salts.

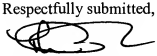
Thus, there is no explicit disclosure that the product of Vincent et al. is a hydrated salt, and due to the steps used in creating the product, such product cannot inherently be such a hydrated salt.

Reconsideration is therefore respectfully requested.

VI. Conclusion

As all rejections and objections have been overcome, Applicants respectfully request passage of this application to allowance. If any fees are necessary to make this application timely and/or complete, such fees may be deducted from Deposit Account No. 19-4375.

Respectfully submitted,



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